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| 09/889,761      | 11/06/2001  | Peter F. Searle      | CACO-0067(P21303US) | 9242             |

7590

09/08/2003

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EXAMINER

BYRD, DEVON R

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 09/08/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/889,761

Applicant(s)

SEARLE, PETER F.

Examiner

Devon R Byrd

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FILE  
COPY

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Claims 1-21 are pending in the present application and are subject to restriction/election of species requirements. NOTE: amended claims resulted in use of U.S. restriction/election practice.

#### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-17, drawn to a method of selecting a nucleic acid encoding a prodrug converting enzyme, classified in class 435, subclass 91.1.
- II. Claim 18, drawn to a nucleic acid molecule encoding a catalytic enzyme or fragment thereof, classified in class 536, subclass 23.1.
- III. Claim 19, drawn to a catalytic enzyme or fragment thereof, classified in class 530, subclass 350+.
- IV. Claims 20 and 21, drawn to a method of cloning a nucleic acid encoding a prodrug converting enzyme or fragment thereof, classified in class 435, subclass 69.1.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in MPEP § 806.05 for inventive groups that are directed to different methods, restriction is deemed proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups I and IV are directed to methods that recite structurally and functionally distinct elements, are not required for one another, and achieve

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different goals. For instance, Group IV requires cloning of a nucleic acid that encodes a prodrug converting enzyme (or fragment thereof), which is not required by Group I.

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product could be made by a materially different process such as chemical synthesis.

Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product could be made by a materially different process, such as isolation from a natural source via chromatographic methods.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP § 806.05 for inventive groups that are directed to different products, restriction is deemed proper because these products appear to constitute patentably distinct inventions for the following reasons: Groups II and III are directed to products that are distinct both physically and functionally, are not required for one another, and are therefore patentably distinct. Further, the enzyme of Group III can be prepared by processes that are materially distinct from the expression of the nucleic acid of Group II, such as by isolation or purification from natural sources. Additionally, the nucleic acid of Group II can be used other than to make the protein of Group III, such as a probe in nucleic acid hybridization assays.

Inventions II and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product could be made by a materially different process such as chemical synthesis.

Inventions III and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product could be made by a materially different process, such as isolation from a natural source via chromatographic methods.

**Because these inventions are distinct for the reasons given above, and**

- a. have acquired a separate status in the art as shown by their different classification;
- b. have different and separately burdensome manual and/or computer structure, name, and bibliographical searches; and,
- c. have divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

***Election of Species (Groups I-IV)***

This application contains claims directed to more than one species of the generic invention.

The species are as follows:

- a) a selectable marker (antibiotic resistance or otherwise) in claim 5;
- b) an enzyme capable of converting a prodrug to its active drug form (e.g., nitroreductase, flavin reductase, DT-diaphorase, thymidine kinase, cytosine deaminase, purine nucleoside phosphorylase) in claim 6;
- c) a specific enzyme of the above elected enzyme capable of converting a prodrug to its active drug form (e.g, the protein encoded by the gene *nfnB*, as disclosed on p 15, ln 14 of the specification)
- d) a prodrug (e.g., CB1954, SN 23862, 2-[N,N-bis(2-iodoethyl)amino]-3,5-dinitrobenzamide, 5-fluorocytosine, acyclovir, gancyclovir, 6-methyl-9-(2-deoxy- $\beta$ -D-erythro-pentofuranosyl) purine) in claim 7;
- e) a single enzyme [from which variants are derived] in claim 9.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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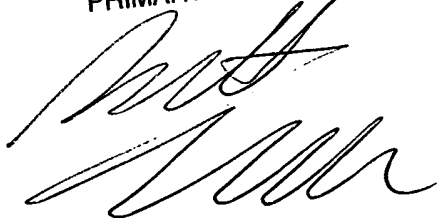
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Devon R Byrd whose telephone number is 703-305-0159. The examiner can normally be reached on Mon-Fri 8a-5p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 703-306-2317. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

DB  
August 29, 2003

BENNETT CELSA  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Bennett Celsa', written over a horizontal line.